

REMARKS

Further and favorable reconsideration of the subject application, in light of the following remarks and pursuant to and consistent with 37 C.F.R. § 1.112, is respectfully requested.

Amendments

Claim 16 was amended to recite that the fluid composition found in part (a) of the kit comprises a biocompatible solvent and a biocompatible polymer, as found in originally presented Claim 1; that the endovascular prosthesis of Claim 17 be included in the claimed kit; and to further recite that this prosthesis is a stent graft as recited in Examples 2 and 3 of the Specification.

In view of this amendment, Claims 17-19 were canceled without prejudice or disclaimer. Applicants reserve the right to file a continuation application directed to the subject matter of these claims.

Claims 20-29 are newly added and correspond in kit form to originally presented Claims 2-11.

These amendments have been made in accordance with 37 C.F.R. § 1.121 as amended on November 7, 2000. As required, attached hereto is an appendix illustrating the changes made to Claim 16.

Entry of these amendments is earnestly solicited.

In view of the above, Claims 16 and 20-29 are now pending in this application.

1. Rejections Under 35 U.S.C. § 102(b)

Claims 16-19 have been rejected under 35 U.S.C. § 102(b) as purportedly anticipated by U.S. Patent No. 5,702,361 to Evans et al. ("Evans"). According to the Examiner, Claims 16-19 are anticipated because "Evans discloses kits for practicing methods of treating vascular lesions comprising a fluid composition capable of forming a fluid mass in the presence of blood, an endovascular prosthesis such as a metal microcoil, and two different size catheters for delivery of the composition and the microcoil (*see* abstract; Column 4, lines 26-47; Column 10, lines 31-41; column 11, lines 52-67; Column 13, lines 1-43)." As indicated above, Claims 17-19 have been canceled without prejudice or disclaimer. The remaining rejection to Claim 16 is respectfully traversed.

To anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984). Applicants maintain that Evans does not anticipate Claim 16 because Evans does not contain all of the elements of Claim 16.

Claim 16 is directed to a kit of parts for use in sealing endoleaks arising from endovascular repair of an aneurysm. Central to this claim is the recitation that the such kits comprise an endovascular prosthesis comprising a stent graft capable of inhibiting blood flow into an abdominal aortic aneurysm.

While admittedly, stents are capable of effecting vascular embolization, there is simply no disclosure in Evans of using an endovascular prosthesis capable of inhibiting blood flow into an abdominal aortic aneurysm. Absent such a disclosure, the rejection under 35 U.S.C. § 102(b) is in error. Withdrawal of this rejection is requested.

2. Rejections Under 35 U.S.C. § 103(a)

Claims 16-19 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,443,454 to Tanabe et al. ("Tanabe") in view of U.S. Patent 5,695,480 to Evans et al. ("Evans II"). According to the Examiner, "it would have been obvious to one of ordinary skill in the art at the time of invention, to prepare a kit comprising Tanabe's liquid substance, and Tanabe's catheter, with a prosthetic device such as those taught by Engelson, because as taught by Tanabe's patent itself, the catheter can be employed in a prosthetic method for treatment of aneurysm. Furthermore one of ordinary skill in the art would have been motivated to prepare a kit, as taught by Evans, to facilitate ease of accessibility in a clinical setting."

In light of this passage, Applicants believe the Examiner intended to include U.S. Patent 5,749,894 to Engelson ("Engelson") in his rejection of Claims 16-19. Applicants respond based on this understanding.

Claims 17-19 have been canceled. Applicants respectfully traverse the rejection to remaining Claim 16.

When applying 35 U.S.C. § 103, four tenets of patent law must be adhered to: (1) the claimed invention must be considered as a whole, (2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination, (3) the references must be viewed without the benefit of impermissible hindsight vision, and (4) a reasonable expectation of success is the standard with which obviousness is determined. *See MPEP § 2141*, citing *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 (Fed. Cir. 1986). Moreover, to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest

all of the claim limitations. *See MPEP § 2142*. Applicants respectfully assert that these tests of obviousness have not been met in this case.

First, the liquid substances of Tanabe are "composed of a reactive liquid substance and other liquid substance capable of reactively hardening the reactive liquid substance." *See Column 5, Lines 25-27*. These substances require exposure to light before hardening. *See Column 5, Lines 33-45*.

The fluid compositions of now presented Claim 16 comprise a biocompatible polymer and a biocompatible solvent that form a coherent mass in the presence of blood due to precipitation of the polymer. The fluid compositions of Claim 16 are in no way dependent upon light exposure for solidification.

Accordingly, Tanabe discloses radically different substances that would not be looked to for guidance in connection with non-photoreactive substances.

In addition to the above, Tanabe fails to disclose an endovascular prosthesis comprising a stent graft capable of inhibiting blood flow into an abdominal aortic aneurysm.

Evans II discloses kits comprising various polymer or prepolymer compositions and a catheter. However, as in Tanabe, Evans II fails to disclose any endovascular prostheses let alone a prosthesis comprising a stent graft capable of inhibiting blood flow into an abdominal aortic aneurysm.

Accordingly, by themselves, either alone or in combination, Tanabe and Evans II fail to create a *prima facie* case of obviousness against now presented Claim 16.

The Examiner also calls upon the prosthesis of Engelson to cure this deficiency in both Tanabe and Evans II. However, Applicants maintain that Engelson does not cure this deficiency.

Simply because Engelson discloses vaso-occlusive devices such as coils and braids (*see Column 1, Lines 5-8*) does not mean that the 35 U.S.C. § 103 inquiry is satisfied. Mere identification of each claimed element in the prior art is not sufficient to negate patentability. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Instead, there "must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 536 (Fed. Cir. 1998). Otherwise, sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. *Rouffet*, 149 F.3d at 1357.

Here, there is no motivation or suggestion within Tanabe, Evans II, or Engelson to select the particular elements and then combine them as suggested by the Examiner. As indicated above, Tanabe discloses different compositions and Evans II is not at all concerned with any endovascular prostheses let alone a prosthesis comprising a stent graft capable of inhibiting blood flow into an abdominal aortic aneurysm. Engelson is also directed at remedying a different medical condition, and does not explain why the problems of Tanabe and Evans II would be overcome.


In sum, looking at the cited publications as whole and at Claim 16 as a whole, there is no suggestion or motivation within the cited publications to combine and modify them as the Examiner proposes. Moreover, even if one were to have considered such combination and modification, he would have had no reasonable expectation in arriving at a successful kit for sealing endoleaks. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection against Claim 16.

CONCLUSION

From the foregoing, further and favorable consideration in the form of a Notice of Allowance is respectfully requested and earnestly solicited.

In the event that there are any questions relating to this response, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,
BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 
Efin M. Dunston
Registration No. 51,147

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: July 15, 2002



Application No. 09/954,789

Attorney's Docket No. 018413-378

Page 1

Attachment to Reply and Amendment Dated July 15, 2002

Marked-up Copy

16. (Amended) A kits of parts for use in sealing endoleaks arising from endovascular repair of an aneurysm which comprises:

(a) a fluid composition which forms a coherent mass in the presence of blood which mass adheres to the vascular surface and/or the surface of the endovascular prosthesis wherein said fluid composition comprises a biocompatible solvent and a biocompatible polymer;

(b) a catheter suitable for delivering the fluid composition to an endoleak site formed from endovascular repair of an aneurysm; [and]

(c) a catheter suitable for delivering an endovascular prosthesis to the aneurysm; and

(d) an endovascular prosthesis comprising a stent graft capable of inhibiting blood flow into an abdominal aortic aneurysm.